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510(k) SUMMARY

510(k) number: K053335

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Date summary prepared: January 30, 2006

Name of the device: Premier Platinum HpSA PLUS
Enzyme Immunoassay for the detection of *H. pylori* antigen in human stool specimens

Classification: LYR, CFR section 866.3110

Predicate device to which this device is being compared: Premier Platinum HpSA (Meridian Bioscience, Inc., Cincinnati, OH) **(K980076, K983255)**

Device description: Premier Platinum HpSA PLUS is an in vitro diagnostic, microwell-based, enzyme-linked immunoassay for the detection of *Helicobacter pylori* antigen in human stool. The assay is intended for use in clinical laboratories to test for bacterial colonization to aid diagnosis, or monitor a patient's response during therapy to eradicate infection. The assay consists of Microwells coated with specific antibodies (solid phase/capture antibodies), Enzyme Conjugate (detector antibodies), Sample Diluent, Premier 20X Wash Buffer I, Premier Substrate Solution I, Premier Stop Solution I and Positive Control. Sample Diluent also functions as the Negative Control reagent.

No calibrators are needed to use this device.

Intended use: The Premier Platinum HpSA PLUS enzyme immunoassay (EIA) is an in vitro qualitative procedure for the detection of *Helicobacter pylori* antigens in human stool. Test results are intended to aid in the diagnosis of *H. pylori* infection and to monitor response during and post-therapy in patients. Accepted medical practice recommends that testing by any current method, to confirm eradication, be done at least four weeks following completion of therapy.

There is no change to the intended use of this device from its predicate.

Comparison charts (Premier Platinum HpSA PLUS vs Predicate Device):

Characteristics	***Premier Platinum HpSA PLUS***	***Premier Platinum HSA (predicate)***
Device Type		
In vitro diagnostic device	Yes	Yes
Control	Includes external control reagent	Includes external control reagent
Calibrator	No	No
Intended Use		
Detection of *H. pylori* antigen	Yes	Yes
Screening test	Yes	Yes
Diagnostic test	No	No
Monitoring therapy	Yes	Yes
Acceptable Sample		
Stool	Yes	Yes

Laboratory Equivalence with (Predicate Device) Combined Totals	Premier Platinum HpSA PLUS	Predicate
Agreement, positive tests	100%	N/A
Agreeement, negative tests	94.8%	N/A
Agreement, overall	96.5%	N/A
Performance characteristics		
Precision/Reproducibility (intra-assay)	97%	100%
Linearity/reportable range	N/A	N/A
Analytical limit of detection/sensitivity	≥ 4.67 ng in stool	≥ 184 ng in stool
Assay cutoff	0.100 at $OD_{450/630}$	0.120 at $OD_{450/630}$
Indeterminant range	None	0.100 – 0.120 at $OD_{450/630}$

Interpretation of test results
The results of bench tests were read using a standard laboratory dual wave length spectrophotometer. Results were interpreted according to the following scale:

Spectrophotometric dual wavelength (450/630 nm)
Negative < 0.100
Positive ≥ 0.100

Results occurring in the 0.100 to 0.120 OD range were tracked to determine if a significant number of results were obtained such that would justify the inclusion of an equivocal range. The absence of equivocal results in the studies showed that this criteria was not necessary.

Analytical sensitivity – limit of detection
Study design: Serial dilutions of purified *H. pylori* flagellar antigen and a *H. pylori* bacterial strain (ATCC 43504) were prepared in stool or Sample Diluent and used to determine the lowest concentration of antigen that would still yield a definitive positive result ($A_{450/630} \geq 0.100$ on Premier Platinum HpSA PLUS). Final concentrations were calculated from the data points using linear regression analysis. **Conclusions to the study:** The analytical limit for *H. pylori* flagellar antigen is 4.67 ng/mL in stool and 0.69 ng/mL in sample diluent. The limit for *H. pylori* bacterial strain is 1.0×10^6 organisms/mL in stool and 4.4×10^4 organisms/mL in Sample Diluent. The limits are lower than those reported for the Predicate Device.

Linearity
Linearity does not apply to the endpoint produced by this device.

Interfering substance testing

Drugs, Nonmicrobial Substances
Study design: Selected drugs and other nonmicrobial substances that might be present in stool specimens were added to five known *H. pylori*-positive and five known negative samples. The final concentrations of the additives per 500 uL of human stool are as follows: TUMS - 10 mg, Mylanta - 0.84 mg, Pepto Bismol - 0.35 mg, Tagamet - 1 mg, Prilosec OTC - 1 mg, barium sulfate - 10 mg, whole blood - 100 uL, mucin - 6.7 mg, human hemoglobin (to make dark stool) – 15 mg, steric + palmitic acids (to make fatty stool) – 7.9 mg. The spiked samples were tested in triplicate and in parallel with an unspiked control. Acceptance criteria required that the values within replicates be similar to each other and to the value obtained with the unspiked specimen. None of the potentially interfering substances had a significant effect on positive or negative test results. Values correlated closely with unspiked samples. **Conclusions to the study:** Drugs or nonmicrobial substances that might be present as co-contaminants of stool samples do not adversely affect results obtained with Premier Platinum HpSA PLUS. These data correlate with data published for the predicate device.

Microbial/Viral organisms (potentially cross-reactive or interfering species)
Study design: The bacteria, yeast and viruses selected were those that might be expected to be present in human stool samples either as part of normal flora or from a disease state. The final concentration of bacteria

or yeast in each sample was ≥ #4 McFarland Standard (1.2 X 10^9 organisms/mL). The final concentration of viruses in each sample was not determined. Unspiked samples were tested in parallel to provide a reference against which the reactions with spiked samples could be compared. Samples were tested in triplicate. Acceptance criteria required that the values within replicates be similar to each other and to the value obtained with the unspiked specimen. See data in Tables below. None of the potential co-contaminants adversely affected the final positive or negative test results. **Conclusions to the study**: Microbial and viral organisms that might be present as co-contaminants of stool samples do not adversely affect results obtained with Premier Platinum HpSA PLUS. These data correlate with data published for the predicate device.

Effects of various microbial organisms on positive test results.

Sample	42				32			
	Run 1	Run 2	Run 3	Avg	Run 1	Run 2	Run 3	Avg
No Spike	0.465	0.409	0.415	0.430	1.472	1.316	1.099	1.296
No Spike	0.536	0.553	0.494	0.528	1.861	1.979	1.900	1.913
No Spike	0.417	0.468	0.403	0.429	1.464	1.550	1.706	1.573
No Spike	0.445	0.460	0.478	0.472	1.308	1.345	1.562	1.405
No Spike	NT	NT	NT	NT	1.412	1.468	1.330	1.403

NT = not tested

Sample	42				32			
	Run 1	Run 2	Run 3	Avg	Run 1	Run 2	Run 3	Avg
Adenovirus	0.460	0.438	0.412	0.437	1.517	1.511	1.340	1.456
Aeromonas hydrophila	0.508	0.557	0.469	0.511	1.837	1.766	1.860	1.821
Borrelia burgdorferi	0.480	0.306	0.0.293	0.360	1.239	1.307	1.230	1.259
Campylobacter lari	0.421	0.522	0.410	0.451	1.721	1.733	1.848	1.767
Campylobacter fetus	NT	NT	NT	NT	1.505	1.633	1.623	1.587
Campylobacter jejuni	NT	NT	NT	NT	1.544	1.378	1.489	1.470
Campylobacter jejuni 2	NT	NT	NT	NT	1.520	1.526	1.396	1.481
Campylobacter jejuni solution	NT	NT	NT	NT	1.402	1.661	1.612	1.558
Campylobacter lari	NT	NT	NT	NT	1.594	1.512	1.565	1.557
Candida albicans	0.452	0.436	0.423	0.437	1.682	1.642	1.839	1.721
Citrobacter freundii	0.563	0.557	0.527	0.549	2.264	2.264	2.181	2.236
Clostridium difficile	0.543	0.600	0.516	0.553	1.878	1.996	2.047	1.974
Clostridium perfringens	0.514	0.496	0.516	0.509	1.799	1.833	1.922	1.851
Enterobacter cloacae	0.428	0.572	0.553	0.518	2.373	2.374	2.469	2.405
Enterococcus faecalis	0.506	0.517	0.555	0.526	2.033	1.963	2.134	2.043
Escherichia coli 0157:H7	0.569	0.534	0.527	0.543	2.177	2.228	2.243	2.216
Escherichia coli 8739	0.500	0.263	0.499	0.421	1.882	1.890	1.952	1.908
Escherichia coli 9637	0.493	0.536	0.498	0.509	1.850	1.782	1.864	1.832
Escherichia fergusonii	0.533	0.528	0.517	0.526	2.237	2.167	2.124	2.176
Escherichia hermannii	0.437	0.440	0.378	0.418	1.469	1.643	1.714	1.609
Escherichia hermannii EMDi-64	0.488	0.436	0.443	0.456	1.838	1.530	1.748	1.705
Helicobacter pylori	OUT*	OUT	OUT	OUT	OUT	OUT	OUT	OUT
Klebsiella pneumoniae	0.533	0.534	0.519	0.529	2.051	2.269	2.153	2.158
Lactobacillus lactis	0.474	0.456	0.420	0.450	1.486	1.642	1.684	1.604
Listeria monocytogenes	0.441	0.427	0.391	0.420	1.672	1.623	1.582	1.626
Peptostreptococcus anaerobius	0.422	0.341	0.381	0.381	1.559	1.481	1.516	1.519
Proteus vulgaris	0.509	0.487	0.476	0.491	1.880	1.950	1.962	1.931

Sample	42				32			
	Run 1	Run 2	Run 3	Avg	Run 1	Run 2	Run 3	Avg
Pseudomonas aeruginosa	0.217	0.560	0.536	0.438	2.208	2.272	2.158	2.213
Pseudomonas fluorescens	0.448	0.427	0.460	0.445	1.620	1.785	1.749	1.718
Rotavirus	0.384	0.407	0.445	0.412	1.356	1.361	1.387	1.368
Salmonella enterica serovar Hilversum	0.441	0.433	0.429	0.434	1.290	1.661	1.617	1.523
Salmonella enterica subsp. *Enterica serovar Hilversum*	0.519	0.537	0.534	0.530	2.232	2.281	2.336	2.283

Sample	42				32			
	Run 1	Run 2	Run 3	Avg	Run 1	Run 2	Run 3	Avg
Salmonella enterica subsp. *Enterica serovar Minnesota*	0.565	0.505	0.600	0.557	2.512	2.529	2.296	2.446
Salmonella Group B	0.413	0.431	0.388	0.411	1.632	1.597	1.784	1.671
Salmonella typhimurium	0.549	0.588	0.569	0.569	2.336	2.180	2.215	2.244
Serratia liquefaciens	0.445	0.429	0.457	0.444	1.508	1.610	1.653	1.590
Serratia liquefaciens	0.482	0.541	0.503	0.509	2.180	1.990	2.125	2.098
Serratia marcescens	0.393	0.470	0.329	0.397	1.019	1.411	1.617	1.349
Shigella boydii	0.540	0.552	0.520	0.537	2.171	2.091	2.235	2.166
Shigella flexneri	0.365	0.549	0.562	0.492	2.321	2.317	2.337	2.325
Shigella dysenteriae	0.536	0.534	0.535	0.535	2.294	2.241	2.275	2.270
Shigella sonnei	0.420	0.465	0.325	0.403	1.598	1.606	1.564	1.589
Staphylococcus aureus	0.618	0.526	0.527	0.557	2.243	2.255	2.189	2.229
Staphylococcus aureus (Cowans 1)	0.505	0.461	0.477	0.481	1.919	1.805	1.808	1.844
Staphylococcus epidermidis	0.587	0.518	0.570	0.558	2.294	2.200	2.121	2.205
Streptococcus faecalis	0.501	0.513	0.469	0.494	1.963	1.965	1.954	1.961
Yersinia enterocolitica	0.500	0.543	0.504	0.516	1.985	1.881	1.490	1.785
Yersinia enterocolitica	0.503	0.490	0.491	0.495	1.974	1.762	1.992	1.909

***Note:** "> 3.000" signifies the signal exceeded the high limit of the plate reader. The limit of the plate reader used in the study was $A_{450/630}$ 2.999.

Sample	2-128			
	Run 1	Run 2	Run 3	Avg
Unspiked Sample	0.386	0.382	0.323	0.364
Campylobacter lari	0.399	0.398	0.390	0.396
Campylobacter jejuni	0.468	0.442	0.456	0.455
Campylobacter jejuni solution	0.432	0.427	0.409	0.423
Campylobacter jejuni 2	0.414	0.410	0.393	0.406
Campylobacter fetus	0.398	0.427	0.383	0.403

Sample	2-42			
	Run 1	Run 2	Run 3	Avg
No Spike	0.011	0.009	0.014	0.011
No Spike	0.006	0.005	0.008	0.006
No Spike	0.006	0.007	0.014	0.009
No Spike	0.005	0.007	0.007	0.006
No Spike	0.006	0.008	0.006	0.007

Sample	2-42			
	Run 1	Run 2	Run 3	Avg
Adenovirus	0.007	0.007	0.006	0.007
Aeromonas hydrophila	0.004	0.006	0.006	0.005
Borrelia bergdorferi	0.012	0.006	0.007	0.008
Campylobacter lari	0.008	0.007	0.004	0.006
Campylobacter fetus	0.007	0.008	0.004	0.006
Campylobacter jejuni	0.016	0.006	0.008	0.010
Campylobacter jejuni 2	0.000	0.006	0.007	0.004
Campylobacter jejuni solution	0.004	0.009	0.007	0.007
Campylobacter lari	0.005	0.007	0.006	0.006
Candida albicans	0.006	0.008	0.008	0.007
Citrobacter freundii	0.005	0.016	0.006	0.009
Clostridium difficile	0.010	0.011	0.009	0.010
Clostridium perfringens	0.010	0.008	0.008	0.009
Enterobacter cloacae	0.003	0.003	0.004	0.003
Enterococcus faecalis	0.002	0.002	0.007	0.004
Escherichia coli 0157:H7	0.005	0.034	0.064	0.034
Escherichia coli 8739	0.005	0.005	0.007	0.006
Escherichia coli 9637	0.003	0.007	0.006	0.005
Escherichia fergusonii	0.004	0.002	0.007	0.004
Escherichia hermannii	0.008	0.007	0.008	0.008
Escherichia hermannii EMDi-64	0.006	0.008	0.007	0.007
Helicobacter pylori	> 3.000	> 3.000	> 3.000	> 3.000
Klebsiella pneumoniae	0.004	0.004	0.007	0.005
Lactobacillus lactis	0.007	0.007	0.017	0.010
Listeria monocytogenes	0.008	0.005	0.009	0.007
Peptostreptococcus anaerobius	0.008	0.008	0.009	0.008
Proteus vulgaris	0.004	0.000	0.007	0.004
Pseudomonas aeruginosa	0.011	0.026	0.021	0.019
Pseudomonas fluorescens	0.006	0.007	0.007	0.007
Rotavirus	0.006	0.005	0.005	0.005
Salmonella enterica serovar Hilversum	0.008	0.007	0.009	0.008
Salmonella enterica subsp. *Enterica serovar Hilversum*	0.002	0.010	0.045	0.019
Salmonella enterica subsp. *Enterica serovar Minnesota*	0.005	0.008	0.005	0.006
Salmonella Group B	0.007	0.006	0.007	0.007

Sample	2-42			
	Run 1	Run 2	Run 3	Avg
Salmonella typhimurium	0.003	0.007	0.005	0.005
Serratia liquefaciens	0.007	0.007	0.007	0.007
Serratia liquefaciens	0.000	0.003	0.004	0.002
Serratia marcescens	0.007	0.008	0.008	0.008
Shigella boydii	0.006	0.000	0.003	0.003
Shigella flexneri	0.004	0.027	0.004	0.012
Shigella dysenteriae	0.006	0.005	0.050	0.020
Shigella sonnei	0.007	0.002	0.009	0.006
Staphylococcus aureus	0.008	0.004	0.008	0.007
Staphylococcus aureus (Cowans 1)	0.007	0.009	0.007	0.008
Staphylococcus epidermidis	0.008	0.003	0.007	0.006
Streptococcus faecalis	0.006	0.005	0.007	0.006
Yersinia enterocolitica	0.005	0.004	0.008	0.006
Yersinia enterocolitica	0.004	0.003	0.006	0.004

Performance Evaluation Data Summarized

Comparison of Premier Platinum HpSA PLUS to Premier Platinum HpSA: Tests with 291 samples from symptomatic patients collected either prior to or following treatment were used to demonstrate that Premier Platinum HpSA PLUS performed similarly to Premier Platinum HpSA. Thirty three of these samples were originally evaluated in an earlier trial to demonstrate the effectiveness of Premier Platinum HpSA. Test performance including 95% confidence intervals is detailed in the following table.

	PP HpSA		
PP HpSA PLUS	**Positive**	**Negative**	**Indeterminate**
Positive	94	10	3
Negative	0	183	1
		95% CI	
Correlation	277/287 (96.5%)	93.7% - 98.3%	
Agreement	Positive test	94/94 = 100%	
	Negative test	183/193 = 94.8%	

Eight of the ten samples that were positive by Premier Platinum HpSA PLUS, but negative by Premier Platinum HpSA, were positive by CLO, histology or UBT testing. The three samples that were positive by Premier Platinum HpSA PLUS but indeterminate by Premier Platinum HpSA were positive by CLO, histology or UBT testing. The one sample that was negative by Premier Platinum HpSA PLUS but indeterminate by Premier Platinum HpSA was negative by CLO, histology or UBT testing.

Analysis of samples producing discordant results

Samples producing discordant results between Premier Platinum HpSA PLUS and the predicate were evaluated against test data from other conventional tests such as CLO, Histology, or UBT to determine the trueness of the results. The results of that evaluation are provided shown in the Table below.

Sample Number	PP HpSA PLUS Results	CLO/Histology/UBT Results	PP HpSA Results (Predicate)	Interpretation using CLO/Hist/UBT
UC82	Positive	Negative	Negative	FP--PPHpSAPLUS
2	Positive	Positive	Indeterminate	TP--PPHpSAPLUS
3-44	Negative	Negative	Indeterminate	TN--PPHpSAPLUS
U082	Positive	Positive	Negative	TP--PPHpSAPLUS
U004	Positive	Positive	Negative	TP--PPHpSAPLUS
U120	Positive	Positive	Negative	TP--PPHpSAPLUS
U159	Positive	Positive	Negative	TP--PPHpSAPLUS
U056	Positive	Positive	Negative	TP--PPHpSAPLUS
U137	Positive	Positive	Indeterminate	TP--PPHpSAPLUS
U161	Positive	Positive	Negative	TP--PPHpSAPLUS
P026	Positive	Positive	Negative	TP--PPHpSAPLUS
P040	Positive	Negative	Negative	FP--PPHpSAPLUS
P172	Positive	Positive	Indeterminate	TP--PPHpSAPLUS
P173	Positive	Positive	Negative	TP--PPHpSAPLUS

Legend: FP = false positive, TP = true positive, TN = true negative

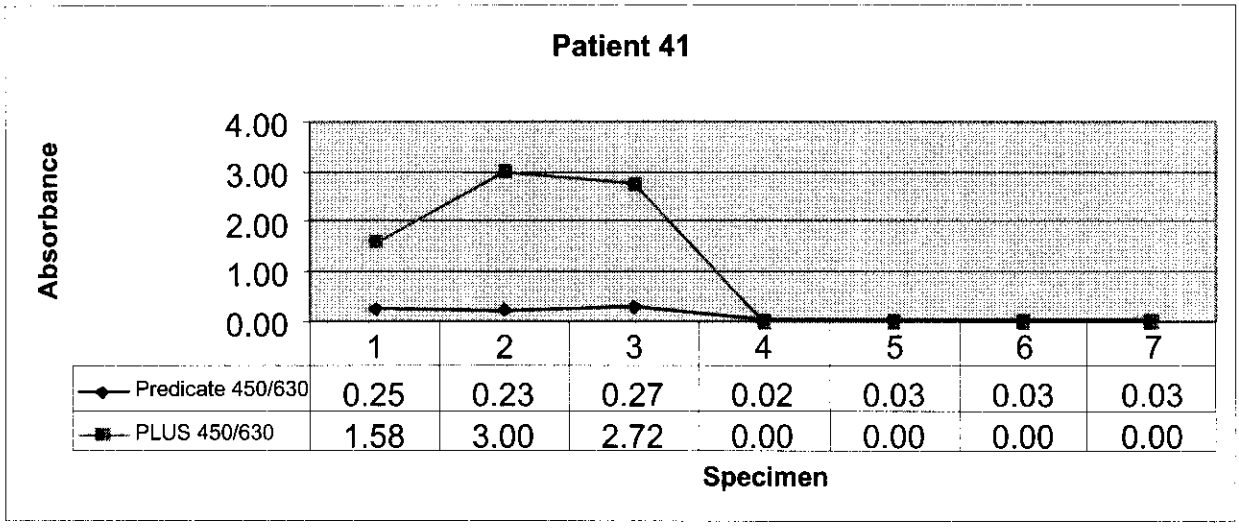
Performance Comparison Table

Performance Characteristics (rounded) in Direct Comparison to Clinical Status or Condition	Premier Platinum HpSA PLUS	Premier Platinum HpSA (Predicate)
Estimated Clinical Sensitivity	N/A	96.1%
Estimated Clinical Specificity	N/A	95.7%
Predictive Value of a Positive Test	N/A	96.1%
Predictive Value of a Negative Test	N/A	95.7%
Laboratory Equivalence with (Predicate Device) Combined Totals		
Agreement, positive tests	100%	N/A
Agreement, negative tests	94.8%	N/A
Correlation	96.5%	95.9%
Performance characteristics		
Precision/Reproducibility	100%	100%
Linearity/reportable range	N/A	N/A
Limit of detection	≥ 4.67 ng in stool	≥ 184 ng in stool
Assay cutoff	0.100 at $OD_{450/630}$	0.120 at $OD_{450/630}$

Therapeutic Monitoring

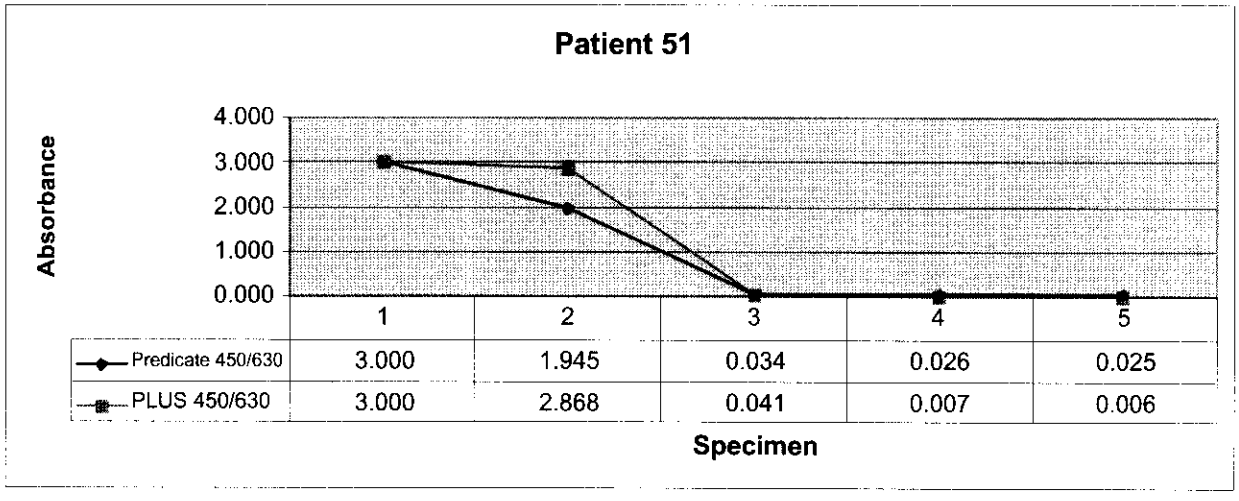
Study design: A panel of frozen, archival specimens from four patients who were monitored during eradication therapy and tested using the predicate Premier Platinum HpSA (K980076 and K983255) were assessed using the Premier Platinum HpSA PLUS assay. One of the panels represented a low positive state with the predicate at the beginning of eradication therapy (See Figure 1.) The remaining three panels represented strongly positive states. (See Figures 2-4.) That data obtained with Premier Platinum HpSA PLUS was compared to that originally obtained with the predicate. In the case of strongly positive samples, the eradication curves for the two tests are substantively the same. The eradication curve for Premier Platinum HpSA PLUS differs from that of the predicate with low positive samples at the beginning of therapy since it produces stronger test results. However, by week four following treatment, the curves are identical. **Conclusions to the study:** Premier Platinum HpSA performs similarly to the predicate when used to monitor the effectiveness of eradication therapy.

Figure 1.



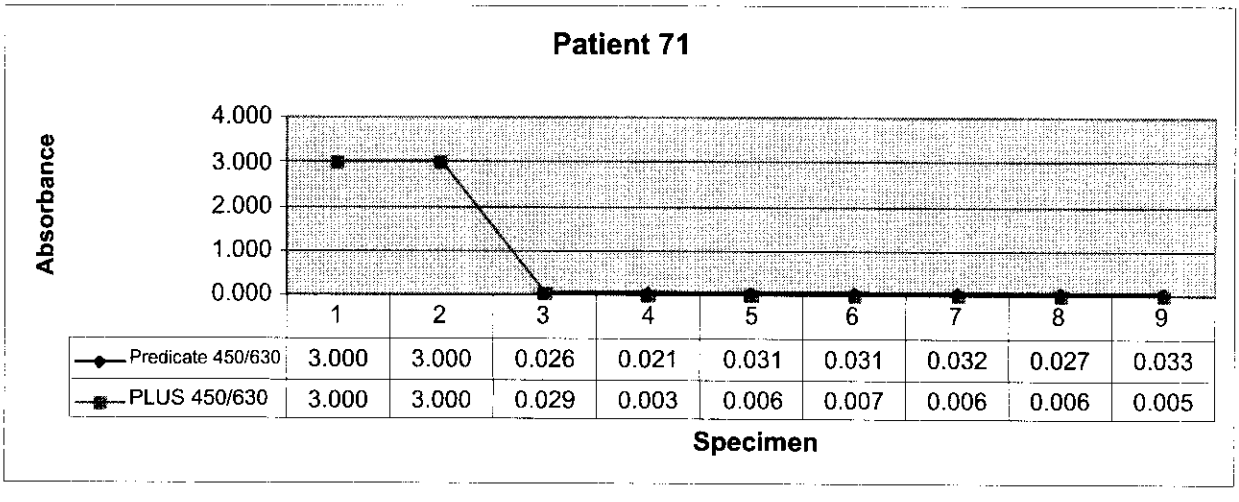
	1	2	3	4	5	6	7
Predicate 450/630	0.25	0.23	0.27	0.02	0.03	0.03	0.03
PLUS 450/630	1.58	3.00	2.72	0.00	0.00	0.00	0.00

Figure 2.



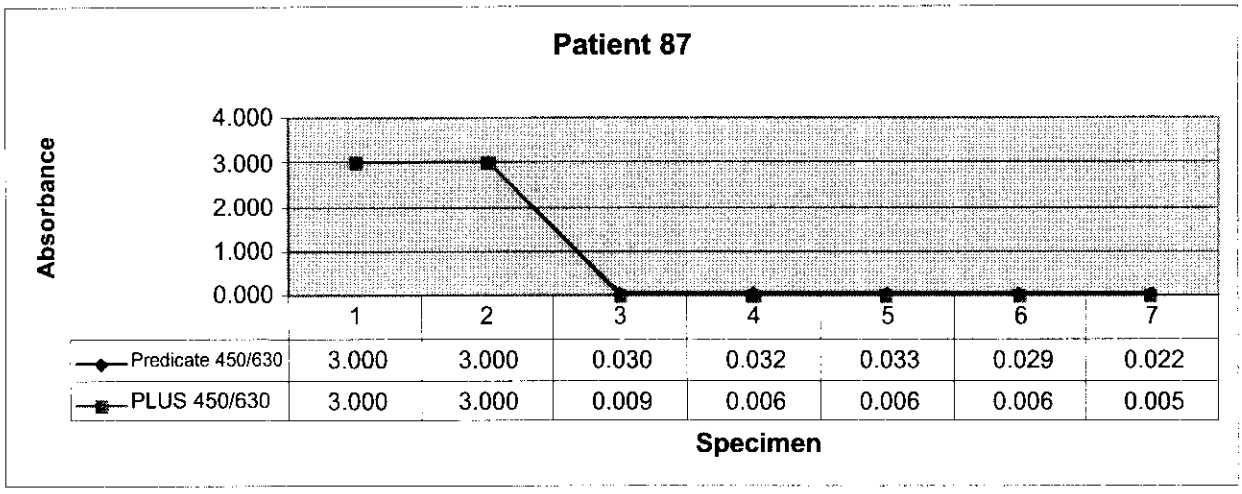
	1	2	3	4	5
Predicate 450/630	3.000	1.945	0.034	0.026	0.025
PLUS 450/630	3.000	2.868	0.041	0.007	0.006

Figure 3.



	1	2	3	4	5	6	7	8	9
Predicate 450/630	3.000	3.000	0.026	0.021	0.031	0.031	0.032	0.027	0.033
PLUS 450/630	3.000	3.000	0.029	0.003	0.006	0.007	0.006	0.006	0.005

Figure 4.



	1	2	3	4	5	6	7
Predicate 450/630	3.000	3.000	0.030	0.032	0.033	0.029	0.022
PLUS 450/630	3.000	3.000	0.009	0.006	0.006	0.006	0.005

Reproducibility

Assay precision, intra-assay variability and inter-assay variability were assessed with a reference panel prepared from high positive samples (n = 2), low low negative samples (n = 2), and low positive and high negative specimens (n = 1 each). The latter were diluted to near the assay limit of sensitivity. Nine replicates each of the low positive and high negative samples were included in the panel to bring the total cohort to 22 reference specimens. Each reference specimen was coded to prevent its identification during testing. Each was evaluated twice per day for three consecutive days by three different laboratories. In accordance with the IFU, values of < 0.100 are interpreted as negative when results are read at A450/630.

High negative samples (OD values just below 0.100) produced weakly positive results (OD values just above 0.100) in 42 out of 162 times tests. It is expected that high negative samples tested at the cut-off will produce weakly positive results 50% of the time. (See EP12-A, User protocol for evaluation of qualitative performance; approved guideline; NCCLS/CLSI, Vol. 22, no.14, 2002.) Low positive, high positive and low negative samples produced the correct results 100% of the time. Reproducibility was 100% with no intra-assay and inter-assay variability for samples prepared above or below the limit of analytical sensitivity.

Results with reproducibility test panel

Results at 450/630 nm		Technologist 1						Technologist 2						Technologist 3					
Sample ID	Sample Qual. Result	Day 1 Run 1	Day 1 Run 2	Day 2 run 1	Day 2 run 2	Day 3 Run 1	Day 3 Run 2	Day 1 Run 1	Day 1 Run 2	Day 2 run 1	Day 2 run 2	Day 3 Run 1	Day 3 Run 2	Day 1 Run 1	Day 1 Run 2	Day 2 run 1	Day 2 run 2	Day 3 Run 1	Day 3 Run 2
1 HP #1	1.510	2.162	1.992	1.830	1.924	1.852	1.754	2.092	1.986	1.941	1.842	1.880	1.745	2.380	2.300	1.962	2.361	2.233	2.364
2 HP #2	1.061	1.445	1.436	1.283	1.318	1.217	1.244	1.537	1.406	1.302	1.307	1.293	1.154	1.858	1.743	1.400	1.698	1.689	1.614
3 Cut off LP #1	0.133	0.217	0.206	0.176	0.230	0.188	0.162	0.274	0.234	0.192	0.203	0.186	0.175	0.292	0.290	0.294	0.289	0.290	0.301
4 Cut off LP #2	0.133	0.206	0.197	0.171	0.214	0.166	0.165	0.271	0.237	0.213	0.189	0.173	0.185	0.310	0.294	0.268	0.273	0.299	0.299
5 Cut off LP #3	0.133	0.179	0.195	0.195	0.207	0.176	0.179	0.197	0.234	0.199	0.185	0.158	0.178	0.318	0.311	0.305	0.298	0.299	0.290
6 Cut off LP #4	0.133	0.185	0.215	0.187	0.210	0.182	0.149	0.265	0.219	0.219	0.175	0.163	0.167	0.295	0.312	0.279	0.308	0.295	0.336
7 Cut off LP #5	0.133	0.180	0.211	0.179	0.210	0.176	0.172	0.243	0.185	0.214	0.164	0.149	0.167	0.286	0.275	0.288	0.318	0.296	0.316
8 Cut off LP #6	0.133	0.201	0.219	0.221	0.220	0.188	0.178	0.239	0.215	0.214	0.146	0.137	0.156	0.300	0.292	0.287	0.315	0.305	0.318
9 Cut off LP#7	0.133	0.207	0.187	0.206	0.203	0.189	0.131	0.217	0.220	0.203	0.140	0.133	0.158	0.293	0.291	0.306	0.287	0.308	0.300
10 Cut off LP #8	0.133	0.186	0.187	0.202	0.223	0.179	0.163	0.233	0.201	0.211	0.118	0.097	0.140	0.309	0.307	0.267	0.298	0.290	0.299
11 Cut off LP #9	0.133	0.193	0.192	0.175	0.173	0.159	0.156	0.238	0.200	0.204	0.140	0.124	0.145	0.331	0.317	0.301	0.298	0.315	0.314
12 Cut off HN #1	0.075	0.094	0.104	0.074	0.121	0.076	0.078	0.131	0.097	0.098	0.059	0.060	0.066	0.096	0.094	0.096	0.094	0.095	0.090
13 Cut off HN #2	0.075	0.101	0.103	0.069	0.105	0.074	0.074	0.152	0.112	0.083	0.090	0.097	0.105	0.081	0.093	0.095	0.093	0.085	0.094
14 Cut off HN #3	0.075	0.073	0.104	0.088	0.092	0.082	0.071	0.161	0.118	0.090	0.105	0.088	0.101	0.074	0.086	0.084	0.081	0.087	0.091
15 Cut off HN #4	0.075	0.058	0.109	0.096	0.079	0.080	0.090	0.142	0.115	0.094	0.105	0.083	0.099	0.096	0.081	0.096	0.087	0.089	0.084
16 Cut off HN #5	0.075	0.080	0.109	0.090	0.089	0.085	0.071	0.147	0.112	0.102	0.079	0.073	0.103	0.092	0.093	0.093	0.089	0.090	0.081
17 Cut off HN #6	0.075	0.083	0.116	0.090	0.101	0.098	0.087	0.137	0.111	0.107	0.085	0.073	0.091	0.090	0.098	0.093	0.091	0.093	0.082
18 Cut off HN #7	0.075	0.088	0.113	0.089	0.113	0.088	0.097	0.128	0.101	0.113	0.064	0.068	0.083	0.082	0.081	0.094	0.080	0.089	0.081
19 Cut off HN #8	0.075	0.098	0.118	0.095	0.089	0.088	0.098	0.140	0.105	0.118	0.060	0.058	0.083	0.089	0.082	0.096	0.085	0.093	0.078
20 Cut off HN #9	0.075	0.090	0.103	0.083	0.112	0.092	0.091	0.126	0.104	0.109	0.046	0.053	0.069	0.085	0.086	0.091	0.093	0.092	0.088
21 LN #1	0.005	0.005	0.006	0.006	0.005	0.005	0.007	0.001	-0.002	0.004	0.001	0.001	0.002	0.003	0.004	0.003	0.004	0.004	0.003
22 LN #2	0.005	0.004	0.005	0.006	0.006	0.006	0.009	0.001	0.000	0.004	0.001	0.000	0.002	0.005	0.005	0.004	0.005	0.004	0.003
Average high negative value		0.085	0.109	0.140	0.108	0.087	0.088	0.086	0.100	0.102	0.077	0.093	0.088	0.085	0.084	0.073	0.089	0.090	0.085
Average low positive value		0.195	0.201	0.242	0.216	0.304	0.299	0.190	0.210	0.208	0.162	0.288	0.298	0.178	0.162	0.147	0.163	0.300	0.308
Percent Correlation		100%	100%	100%	95%	100%	100%	59%	100%	100%	95%	95%	100%	100%	100%	100%	100%	100%	100%
Correlation of cut off Specimens											97%								

Legend: LP = low positive, HP = High positive, LN = Low negative, HN = High negative,

CONCLUSIONS

Premier Platinum HpSA PLUS:

1. Can be used reliably for the rapid detection of *H. pylori* in human stool specimens
2. Performs similarly to the existing FDA approved Premier Platinum HpSA (K980076 and K983255).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 10 2006

Ms. Susan Rolih
Vice President, Regulatory Affairs and Quality Assurance
Meridian Bioscience, Inc.
3471 River Hills Drive
Cincinnati, OH 45244

Re: k053335
Trade/Device Name: Premier Platinum HpSA PLUS
Regulation Number: 21 CFR 866.3110
Regulation Name: Campylobacter Fetus Serological Reagents
Regulatory Class: Class I
Product Code: LYR
Dated: January 31, 2006
Received: February 1, 2006

Dear Ms. Rolih:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240)276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT
Premier Platinum HpSA PLUS

510(K) Number: K053335

The Premier Platinum HpSA PLUS enzyme immunoassay (EIA) is an in vitro qualitative procedure for the detection of *Helicobacter pylori* antigens in human stool. Test results are intended to aid in the diagnosis of *H. pylori* infection and to monitor response during and post-therapy in patients. Accepted medical practice recommends that testing by any current method, to confirm eradication, be done at least four weeks following completion of therapy.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K053335